## REMARKS

Claims 113, 117-120, 123, 125, 129-135, 137-139, 141-144, 170-175, 180-182, 185, 187, 190-204, 206-209, and 235-257 constitute the pending claims in the present application.

Support for the amendments and new claims can be found throughout the instant specification and claims as filed, for example, at lines 1-19 of page 11; at paragraphs 4-5 of page 12; at lines 10-13 and 28-29 of page 13; at lines 10-26 of page 18; at lines 17-24 of page 20; at paragraph 1 of page 21; at lines 26-30 of page 27, at lines 1-25 of page 28; at lines 13-29 of page 29; at lines 18-20 of page 30; at page 32; at pages 36-37; at lines 25-27 of page 40; at lines 1-12 of page 24; Example 1, and Example 17.

The mouse hybridoma B43.13, which makes the antibody Alt-2, was deposited with the American Type Culture Collection, 10801 University Blvd., Manassas, VA 20110-2209, on May 18, 2000, and was given ATCC deposit number PTA-1883.

Applicant asserts that no new matter has been added to the specification or claims. Applicant reserves the right to prosecute any canceled subject matter in a future application.

Applicant respectfully requests reconsideration of the rejections of record in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

### *Specification*

The title of the abstract was objected to for reciting "Abstract of the Invention". Applicants have amended the title of the abstract as suggested by the Examiner and respectfully request reconsideration and withdrawal of the rejection.

### *35 U.S.C. § 102(e)*

Claims 113, 115-121, 123, 128, 131-135, 137-139, 141-144, 170-175, 177-185, 190, 193-204, 206-209 are rejected under 35 USC § 102(e) as allegedly being anticipated by U.S. Patent No. 5,532,159 (Webb et al., filed April 1, 1994; the "'159 Patent").

The Examiner stated at page 3 of the Office action that "[d]ue to the indefiniteness of the claim language, claims drawn to 'native' antibodies are assumed to encompass any antibody". As claim 128 was the only claim to recite "native antibodies", Applicants assert that the rejection is moot with respect to cancelled claim 128 and does not apply to any other claim.

The Examiner stated at page 3 the '159 Patent "teaches a method for inducing a therapeutic host immune response against a multi-epitopic antigen that does not elicit an effective host immune response comprising contacting a multi-epitopic antigen present in the host's serum (column 10, line 55+, column 17) with a composition comprising a binding agent that specifically binds to a first epitope on the antigen, the binding agent present in the composition being non-radiolabeled, and allowing the binding agent to form a binding agent/antigen pair. Specifically, the patent teaches monoclonal antibody therapy against a cancer cell product, oncofetal protein or 'OFP'. OFP, alone or in-vivo, does not elicit an effective immune response wherein the patent further teaches that OFP may be immunosuppressive (column 2, lines 55+)".

The Examiner stated at page 4 of the Office action that "[a]lthough the patent does not specifically teach that the specific immune response is elicited 'against a second epitope on the antigen in the binding agent/antigen pair' (Claim 113) or elicited 'against the antigen' (Claim 135) or 'wherein the binding agent/antigen complex elicits an effective immune response against the multi-epitopic in vivo antigen' (Claim 174) or that the effective immune response comprises a cellular and or humoral immune response, the method steps described in the prior art comprise the same steps as claimed in the instant invention and the claimed functional limitations would be an inherent property of the referenced method".

Applicants respectfully traverse these statements and point to lines 57-65 of column 2 of the '159 Patent for support of this traversal. The '159 Patent specifically teaches that it "is believed that OFP is immunosuppressive and by ***sequestering or removing OFP via the monoclonal antibody***, the patient's immune defense against tumors is released from impairment allowing a more efficient and natural rejection of the cancer. Monoclonal antibodies to OFP offer a simple and inexpensive agent for use as a ***primary*** or adjuvant therapy". [emphasis added]

Applicants assert that the teachings of the '159 patent differ significantly from the invention of the instant application as described and claimed. The anti-OFP antibodies of the '159 Patent work because they sequester or remove OFP from circulation such that it is no longer available to the immune system. If the complex is unavailable, an effective immune response against a second previously un-exposed epitope of OFP cannot be generated.

The antibodies of the instant application do not work by sequestering or removing an antigen from circulation. As described and claimed in the instant application, upon binding of the binding agent to the multi-epitopic *in vivo* antigen, a binding agent/antigen complex is formed to which an effective immune response is generated. At no point does the '159 Patent teach or suggest that administration of the anti-OFP antibodies generates an effective immune response to an epitope other than the epitope specifically bound by the anti-OFP antibodies. Nor does it teach or suggest that an immune response to a distinct ("altered") second epitope could provide a therapeutic benefit to the patient being treated.

The antibodies of the '159 Patent and the binding agents of the instant application are fundamentally different. Consequently, the method steps described in the prior art do not comprise the same steps as claimed in the instant application, and the claimed functional limitations are not an inherent property of the referenced method. The claims do result in a manipulative difference in the method steps when compared to the prior art disclosure, and are distinguished over the prior art teaching. Thus, Applicants submit that the anti-OFP antibodies of the '159 Patent do not inherently anticipate the instant claims.

Applicants respectfully request reconsideration and withdrawal of the rejection.

***35 U.S.C. § 103(a)***

Claims 113, 115-121, 123-125, 128-135, 137-139, 141-144, 170-175, 177-183, 185, 187, 190-204, 206-209, and 235-239 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baum et al. (Hybridoma, 12(5): 583-589 (1993)) or Madiyalakan et al. (Hybridoma 14(2): (1995)) in further view of U.S. Patent 5,532,159 (Webb et al., filed April 1, 1994).

The Examiner stated at page 5 of the Office action that "[d]ue to the indefiniteness of the claim language, claims drawn to 'native' antibodies are assumed to encompass any antibody". As claim 128 was the only claim to recite "native antibodies", Applicants assert that the rejection is moot with respect to cancelled claim 128 and does not apply to any other claim.

Baum et al. and Madiyalakan et al. teach administration of radiolabeled antibodies or antibody fragments. A person of ordinary skill in the art would recognize that on the face value, Baum et al. and Madiyalakan et al. teach that the radionuclide is the toxic agent and the antibody/fragment is merely a targeting mechanism, not the basis for the therapeutic effect. Thus, Baum et al. and Madiyalakan et al. do not provide any motivation to make a non-radiolabeled antibody or fragment as recited in the instant claims as a therapeutic agent.

The deficiencies of the '159 Patent have been discussed *supra,* and cannot cure the deficiencies of Baum et al. or Madiyalakan et al.

In view of the amendments to the claims, Applicants assert that Baum et al., Madiyalakan et al. and the '159 Patent do not teach or suggest all of the limitations of the instant claims, nor do not they provide any motivation to arrive at the invention as currently claimed.

Applicant respectfully requests reconsideration and withdrawal of the rejection.

## CONCLUSION

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945.**

Respectfully Submitted,

Date: December 23, 2003

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